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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,636	11/25/1997	ELAZAR RABBBANI	ENZ-53(DIV-3	4642

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ENZO DIAGNOSTICS, INC.
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EXAMINER

SCHULTZ, JAMES

ART UNIT PAPER NUMBER

1635

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary

Application No.

08/978,636

Applicant(s)

RABBBANI ET AL.

Examiner

J. Douglas Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004 and 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 245-255 and 258-261 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 245-247, 249-255 and 258-261 is/are rejected.
- 7) ☒ Claim(s) 248 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/27/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's responses filed April 23, 2004 and October 14, 2003 have been considered. Rejections and/or objections not reiterated from the previous office action mailed April 9, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to arguments, Claim Rejections - 35 USC § 102

Claims 245-247, and 249-254 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner *et al.* (of record) for the same reasons of record as cited in the Office action mailed April 9, 2003.

Applicants have traversed the instant rejection by asserting that limitations added to the claims by way of amendment serve to obviate the instant rejection. Specifically, applicants argue that the claim limitations reciting "a nucleic acid sequence which encodes a non-eukaryotic polymerase and contains a non-native intron" are not taught in Wagner, and thus the rejection cannot be maintained.

This is not considered to be convincing. The claim limitations do not serve to free the claim from the prior art because the claim language does not require that the intron be a part of

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the polymerase, but rather requires only that the intron be contained on the nucleic construct. The claim reads as follows:

“1.) A nucleic construct which comprises a nucleic acid sequence which encodes a non-eukaryotic polymerase and contains a non-native intron, wherein said polymerase is expressed solely in a eukaryotic cell and said polymerase is capable of producing more than one copy of a nucleic acid sequence from said construct when introduced into a eukaryotic cell.”

A broad reasonable interpretation of this language does not require the intron to be a part of the polymerase, but rather that an intron be contained somewhere on the construct as a whole. Because Wagner teaches a plasmid (i.e. a nucleic acid construct) that encodes two genes, the first being a gene of interest which includes a genomic gene and therefor contains introns non-native to the construct as a whole (e.g. col. 5, line 40-49), and the second being the non-eukaryotic polymerase T7 which acts to transcribe multiple copies of the gene of interest, Wagner is considered to teach all the instant claim limitations.

Claim Rejections - 35 USC § 102

Claims 255 and 258-261 rejected under 35 U.S.C. 102(b) as being anticipated by Yamashita *et al.* (Agric. Biol. Chem. 1990. 54(11)2801-9).

The invention of the above claims is drawn to a nucleic acid construct which produces a nucleic acid product comprising a non-native intron, which is removed during processing in a eukaryotic cell, and wherein said nucleic acid product or protein expressed from a nucleic acid product would be toxic to a non-eukaryotic cell in the absence of said non-native intron, wherein the nucleic acid product is single-stranded sense RNA.

Yamashita *et al.* teaches a nucleic acid construct which produces a nucleic acid product comprising a non-native intron, which is removed during processing in a eukaryotic cell, and wherein said nucleic acid product or protein expressed from a nucleic acid product would be toxic to a non-eukaryotic cell in the absence of said non-native intron, wherein the nucleic acid product is single-stranded sense RNA (e.g. see abstract and materials and methods).

Allowable Subject Matter

Claim 248 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims for the reasons of record cited in the Office action mailed April 9, 2003.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

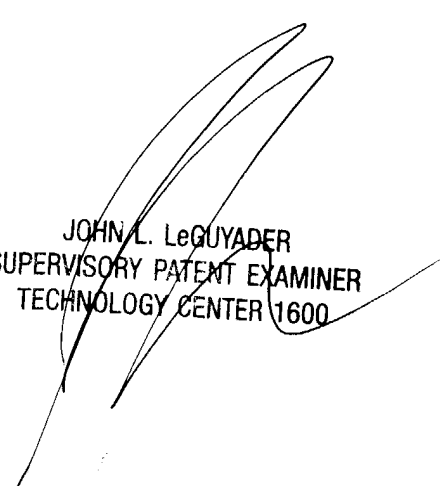
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JD Schultz, PhD



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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